FEB 17 2012

K113505

510(k) SUMMARY

February 7, 2012

CONTACT:
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Greiner Bio-One North America, Inc.
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NAME OF DEVICES:

Trade Name:	**VACUETTE**® QUICKSHIELD with SNAPPY Tube Holder
Common Name:	Evacuated Blood Collection Tube Holder
Classification Name:	Needle, Hypodermic, Single Lumen
CFR Reference No.	21 CFR 880.5570
Product Code:	FMI

PREDICATE DEVICE:
Greiner **VACUETTE**® QUICKSHIELD with SNAPPY Tube Holder – K102774

DEVICE DESCRIPTION:

Intended Use: The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder is to be used together only with VACUETTE® Blood Collection Needles and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. These devices are to be used by properly trained healthcare professionals only in accordance with these instructions.

Product Description: The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder is a non-sterile single-use plastic tube holder. It is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury. VACUETTE® QUICKSHIELD with SNAPPY Tube Holder helps secure VACUETTE® tubes in place during collection. Note: Always follow tube manufacturer's specimen collection instructions for holding tube in place to ensure a complete vacuum draw. These devices are to be used by properly trained healthcare professionals only in accordance with these instructions.

The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder can be used with any size VACUETTE® Multi-Sample Needle:

- Needle gauge = 18G; Front needle length = 38 mm [1 inch]
- Needle gauge = 18G; Front needle length = 38 mm [1 ½ inch]
- Needle gauge = 20G; Front needle length = 38 mm [1 inch]

- Needle gauge = 20G; Front needle length = 38 mm [1 ½ inch]
- Needle gauge = 21G; Front needle length = 25 mm [1 inch]
- Needle gauge = 21G; Front needle length = 38 mm [1 ½ inch]
- Needle gauge = 22G; Front needle length = 25 mm [1 inch]
- Needle gauge = 22G; Front needle length = 38 mm [1 ½ inch]

The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder can be used with the following size VACUETTE® VISIO Blood Collection Needles:

- Needle gauge = 21G; Front needle length = 25 mm [1 inch]
- Needle gauge = 22G; Front needle length = 25 mm [1 inch]
- Needle gauge = 21G; Front needle length = 38 mm [1 ½ inch]
- Needle gauge = 22G; Front needle length = 38 mm [1 ½ inch]

SUBSTANTIAL EQUIVALENCE:

The Greiner **VACUETTE®** QUICKSHIELD with SNAPPY Tube Holder is substantially equivalent to the predicate device in fundamental scientific technology and materials.

This Traditional 510(k) is submitted for a device modification to the Greiner **VACUETTE®** QUICKSHIELD with SNAPPY Tube Holder (K102774, FDA cleared 10/15/2010) to include **VACUETTE®** Multi-Sample Needles as an additional recommended needle type.

Table 1: Substantial Equivalence Comparison Table

	VACUETTE® QUICKSHIELD with SNAPPY Tube Holder (subject of this Traditional 510(k))	**VACUETTE®** QUICKSHIELD with SNAPPY Tube Holder (K102774) (predicate device)
Intended Use	The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder is to be used together only with VACUETTE® Blood Collection Needles and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. These devices are to be used by properly trained healthcare professionals only in accordance with these instructions.	The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder is to be used together only with VACUETTE® VISIO PLUS Blood Collection Needle with View Window and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. These devices are to be used by properly trained healthcare professionals only in accordance with these instructions.
Holder	SNAPPY Tube Holder (21CFR880.5570, Product Code FMI)	Same
Holder Material	Polypropylene, with tabs	Same
Sharp Safety Feature	Polypropylene holder with polypropylene needle locking shield	Same
Safety Feature Activation	Stable surface or thumb	Same

	VACUETTE® QUICKSHIELD with SNAPPY Tube Holder (subject of this Traditional 510(k))	**VACUETTE®** QUICKSHIELD with SNAPPY Tube Holder (K102774) (predicate device)
Sterilization	Non-sterile	Same
Needle Recommenda-tion	**VACUETTE®** VISIO PLUS Blood Collection Needle with View Window (K061483, FDA cleared 8/14/06) **VACUETTE®** Multi-Sample Needles (K973620, FDA cleared 12/17/97)	**VACUETTE®** VISIO PLUS Blood Collection Needle with View Window (K061483, FDA cleared 8/14/06)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Greiner Bio-One North America, Inc.
C/O Ms. Judi Smith, LLC
Principal
P.O. Box 103
Baldwin, Maryland 21013

FEB 17 2012

Re: K113505
Trade/Device Name: **VACUETTE®** QUICKSHIELD with SNAPPY Tube Holder
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 18, 2012
Received: January 19, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

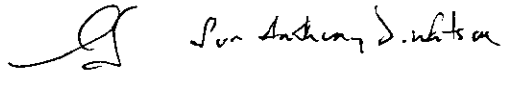
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113505

Device Name: Greiner **VACUETTE®** QUICKSHIELD with SNAPPY Tube Holder

Indication For Use:

Intended Use:

The VACUETTE® QUICKSHIELD with SNAPPY Tube Holder is to be used together only with VACUETTE® Blood Collection Needles and VACUETTE® Blood Collection Tubes as a system in routine venipuncture procedures. These devices are to be used by properly trained healthcare professionals only in accordance with these instructions.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation

510(k) K113505

2/15/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113505